GENERAL ASSEMBLY OF NORTH CAROLINA SESSION 2001

SESSION LAW 2001-469 HOUSE BILL 1472

AN ACT DIRECTING THE DEPARTMENT OF HEALTH AND HUMAN SERVICES TO ESTABLISH A BIOLOGICAL AGENTS REGISTRY, AND IMPOSING CIVIL PENALTIES FOR VIOLATION OF REGISTRY REQUIREMENTS.

The General Assembly of North Carolina enacts:

SECTION 1. Part 1 of Article 6 of Chapter 130A of the General Statutes is amended by adding the following new section to read:

- "§ 130A-149. Biological agents registry; rules; penalties.
- (a) The Department shall establish and administer a program for the registration of biological agents. The biological agents registry shall identify the biological agents possessed and maintained by any person in this State and shall contain other information required under rules adopted by the Commission.
- (b) The following definitions apply in this section:
 - (1) 'Biological agent' means:
 - a. Any select agent that is a microorganism, virus, bacterium, fungus, rickettsia, or toxin listed in Appendix A of Part 72 of Title 42 of the Code of Federal Regulations.
 - b. Any genetically modified microorganisms or genetic elements from an organism on Appendix A of Part 72 of Title 42 of the Code of Federal Regulations, shown to produce or encode for a factor associated with a disease.
 - c. Any genetically modified microorganisms or genetic elements that contain nucleic acid sequences coding for any of the toxins listed on Appendix A of Part 72 of Title 42 of the Code of Federal Regulations, or their toxic submits.
 - (2) 'Person' means any association, business, corporation, facility, firm, individual, institution of higher education, organization, partnership, society, State agency, or other legal entity.
- (c) The Commission shall adopt rules for the implementation of the registry program, as follows:
 - (1) Determining and listing the biological agents required to be reported under this section.
 - (2) Designating persons required to make reports and specific information required to be reported including time limits for reporting, form of reports, and to whom reports shall be submitted.
 - (3) Providing for the release of information in the registry to State and federal law enforcement agencies and the United States Centers for Disease Control and Prevention pursuant to a communicable disease investigation commenced or conducted by the Department, the Commission, or other state or federal law enforcement agency having investigatory authority, or in connection with any investigation involving release, theft, or loss of biological agents.
 - (4) Establishing a system of safeguards that requires persons possessing and maintaining biological agents subject to this section to comply with the same federal standards that apply to persons registered to possess the same agents under federal law.
 - (5) Establishing a process for persons that possess and maintain biological agents to alert appropriate authorities of unauthorized possession or attempted possession of biological

agents. The rules shall designate appropriate authorities for receipt of alerts from these persons.

- (d) Any person that possesses and maintains any biological agent required to be reported under this section shall report to the Department the information required by the Commission for inclusion in the biological agent registry.
- (e) Except as otherwise provided in this section, information prepared for or maintained in the registry under this section shall be confidential and shall not be a public record under G.S. 132-1. The Department may, in accordance with rules adopted by the Commission, release information contained in the biological agent registry for the purpose of conducting or aiding in a communicable disease investigation. The Department shall cooperate with and may share information contained in the biological agent registry with the United States Centers for Disease Control and Prevention, and state and federal law enforcement agencies in any investigation involving the release, theft, or loss of a biological agent required to be reported under this section. Release of information from the registry as authorized under this subsection shall not render the information released a public record under G.S. 132-1. Release of information from the registry as authorized under this subsection also shall not render the information prepared for or maintained in the registry a public record under G.S. 132-1.
- (f) The Department shall impose a civil penalty for a willful or knowing violation of this section in the amount of up to one thousand dollars (\$1,000). Each day of a continuing violation shall be a separate offense. Any person wishing to contest a penalty shall be entitled to an administrative hearing in accordance with Chapter 150B of the General Statutes."

SECTION 2. G.S. 130A-29(c) is amended by adding the following subdivision to read: "(10) Pertaining to the biological agents registry in accordance with G.S. 130A-149."

SECTION 3. This act becomes effective January 1, 2002. In the General Assembly read three times and ratified this the 20th day of November, 2001.

- s/ Beverly E. Perdue President of the Senate
- s/ James B. Black Speaker of the House of Representatives
- s/ Michael F. Easley Governor

Approved 11:14 a.m. this 28th day of November, 2001